NOV 2 0 2003

510(k) Summary Statement **11/17/03**

Device: Guided Growth Plate

Number: K031493

Classification name: orthopedic implant (pediatric)

Patent pending by : Morphpgraphics LC, (Salt Lake City, Utah)

Manufactured by : Precimed Inc. (Chester Springs, Pa)

Description of device: The two hole plate features a contoured waist and low profile for pediatric usage. There is a center hole for accurate application of the plate over a temporary guide pin. This is to facilitate precise and reproducible placement of the implant relative to the adjacent growth plate that is localized radiographically.. The plate is available in two sizes (small / large) to accommodate the variations of bone size and geometry. It is transfixed to the bone using two parallel cannulated titanium screws. The Guided Growth Plate is made out of titanium which is (by design) flexible and compatible with both radiographic imaging and MRI.

Application: The Guided Growth Plate is applied under fluoroscopic or radiographic guidance to the metaphysis /epiphysis of a given bone on the convex side of the deformity. It should be placed sub-muscular but extra-periosteal and is secured with parallel screws. The screws diverge as the deformity corrects with continued growth and the implant is eventually removed. Typically a single plate is applied per level of deformity; this procedure may be repeated as necessary for recurrent deformities.

Indications for use : The Guided Growth Plate is designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children.
Specific conditions / diseases for which the device will be indicated include:

***valgus, varus or flexion, extension deformities of the knee (femur and/or tibia)**
***valgus, varus or plantar flexion deformities of the ankle**
***algus or varus deformities of the elbow (humerus)**
***radial or ulnar deviation, flexion or extension deformities of the wrist (radius)**

Contraindication : The device should not be used for adult deformities; skeletal maturity precludes further growth. Likewise, if a given growth plate has closed due to other causes such as trauma or infection, the guided growth plate will be ineffective and should not be implanted.

Substantial equivalence : The Blount Zimmalloy staple, which is manufactured by Zimmer, Inc (Warsaw, Indiana) has been on the market since 1950. It was designed to inhibit longitudinal growth of the physis (growth plate) and has been commonly employed to correct angular deformities of the extremities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

Peter M. Steven, M.D.
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University of Utah School of Medicine
P.O. Box #58246
Salt Lake City, Utah 84158

Re: K031493
Trade/Device Name: Guided Growth Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: October 15, 2003
Received: October 21, 2003

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031493

Device Name: Guided Growth Plate

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*valgus, varus or plantar flexion deformities of the ankle
*valgus or varus deformities of the elbow (humerus)
*radial or ulnar deviation, flexion or extension deformities of the wrist (radius)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031493